

AUG - 9 1996

InCare Pelvic Floor Therapy System with Desktop Computer**Safety and Effectiveness Summary****1. Submitter's name, Address and Contact Person**

<u>Submitter</u>	<u>Contact Person</u>
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Date Summary Prepared - May 13, 1996

2. Name of Device:

InCare Pelvic Floor Therapy System with Desktop Computer

3. Name of Predicate Device(s)

Hollister PRS9300 Pelvic Floor Therapy System, K930530/C

4. Description of Device

The InCare Pelvic Floor Therapy System with Desktop Computer is an office based instrument that is intended to be used by physicians, nurses, nurse clinicians, and physiotherapists in a physicians office, clinic, or hospital for the purpose of providing electromyographic or pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control for the treatment of female urinary incontinence. The InCare Pelvic Floor Therapy System also provides electrical stimulation capabilities for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of female urinary incontinence.

The "nucleus" of the system is the combination of an instrumentation unit and a desktop computer. Other peripheral devices such as monitors and printers can be added for convenience or ease of use. There is a clear separation of functional control between the two elements of the system. Features or functions that are "data manipulation and presentation" activities are properly associated with the personal computer. Features and functions that are "patient treatment" actions are controlled by the Instrumentation Unit.

The desktop computer and Instrumentation Unit are physically separate devices "linked" to each other by a communication pathway.

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5. Statement of Intended Use

The biofeedback components of the InCare Pelvic Floor Therapy System with Desktop Computer are intended to provide electromyographic or pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control for the treatment of female urinary incontinence.

The electrical stimulation component of the InCare Pelvic Floor Therapy System with Desktop Computer provides stimulation capabilities for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of female urinary incontinence.

6. Statement of Technological Characteristics of the Device

- The InCare Pelvic Floor Therapy System with Desktop Computer and the InCare PRS9300 (K930530\C) are substantially equivalent based upon the following:

1. Intended Use of the two devices are identical.
2. The InCare Pelvic Floor Therapy System with Desktop Computer utilizes the exact same instrumentation unit as the predicate device (InCare PRS9300). The Instrumentation Unit controls features and functions that are patient treatment actions.
3. The InCare Pelvic Floor Therapy System with Desktop Computer utilizes the same software that is used in the predicate device (InCare PRS9300) for the data manipulation and presentation activities associated with the personal computer and the patient therapy actions associated with the Instrumentation Unit.
4. The InCare Pelvic Floor Therapy System with Desktop Computer differs from the predicate device (InCare PRS9300) in one aspect only. The proposed device utilizes a desktop personal computer whereas the predicate device utilizes a laptop personal computer. Because of this difference the communication pathway between the respective computers and the Instrumentation Unit is different.

A chart showing the differences and similarities of the InCare Pelvic Floor Therapy System with Desktop Computer and the predicate device follows on the next page:

InCare Pelvic Floor Therapy System with Desktop Computer

Comparison of the Technological Characteristics of the InCare Pelvic Floor Therapy System with Desktop Computer and the Predicate Device InCare PRS9300 (K930530/c)

Stimulation Characteristics	Predicate device PRS9300 - K930530/C	Proposed device InCare Pelvic Floor Therapy System w/ Desktop Computer
Intended Use	Treatment of Urinary Incontinence	Treatment of Urinary Incontinence
Computer Type (see Exhibit I, Section VI, page 29)	Laptop Computer	Desktop Computer
Output (nominal)	0-30 VDC	0-30 VDC
Waveform	Square, Symmetrical, Balanced, Biphasic	Square, Symmetrical, Balanced, Biphasic
charge/pulse at 500 Ω	60 μ C/phase; net charge/pulse = 0	60 μ C/phase; net charge/pulse = 0
Frequency	12.5, 20, 50, 100 Hz	12.5, 20, 50, 100 Hz
Peak Pulse Intensity	30 VDC	30 VDC
Pulse width	0.3, 1 ms	0.3, 1 ms
Ramps	20%, 40%, 60%, 80%, 100% of "ON" time (no down ramping)	20%, 40%, 60%, 80%, 100% of "ON" time (no down ramping)
Duty Cycle	On (sec): 1-80 in 1 sec increments Off (sec): 0 - 80 in 1 sec increments	On (sec): 1-80 in 1 sec increments Off (sec): 0 - 80 in 1 sec increments
Session Duration (min)	0-30, 1 minute increments	0-30, 1 minute increments
Programmable Features	NONE BY PATIENT	NONE BY PATIENT
	By Physician: Pulse width, Frequency, Duty Cycle, Session length	By Physician: Pulse width, Frequency, Duty Cycle, Session length
Current Density Conditions: Full output setting, 100Hz, 1ms pulse width at 500 ohms (nominal)	Probe 9595 - 0.003 amperes/cm ² Probe 9596 - 0.018 amperes/cm ²	Probe 9595 - 0.003 amperes/cm ² Probe 9596 - 0.018 amperes/cm ²
Power Density Conditions: Full output setting, 100Hz, 1ms pulse width at 500 ohms (nominal)	Probe 9595 - 0.047 watts/cm ² Probe 9596 - 0.239 watts/cm ²	Probe 9595 - 0.047 watts/cm ² Probe 9596 - 0.239 watts/cm ²
EMI	Engineering models of PRS9300 have been tested and shown to comply with EN 55011 and IEC 801-3 emissions and immunity, respectively.	**See note on following page

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Biofeedback Characteristics	Predicate device PRS9300 - K930530/C	Proposed device InCare Pelvic Floor Therapy System w/ Desktop Computer
Intended Use	Treatment of Urinary Incontinence	Treatment of Urinary Incontinence
Measurement Channels	Adjustable, 2 channels EMG, 2 channels pressure, or combination EMG and pressure	Adjustable, 2 channels EMG, 2 channels pressure, or combination EMG and pressure
EMG Sensitivity (microvolts)	0-5, 0-10, 0-25, 0-50, 0-100, 0-250, 0-500	0-5, 0-10, 0-25, 0-50, 0-100, 0-250, 0-500
EMG Bandwidth	100-500 Hz	100-500 Hz
EMG Signal Processing	Root Mean Squared (RMS)	Root Mean Squared (RMS)
EMG Detection	Bipolar	Bipolar
Pressure Sensitivity (cm-H ₂ O)	0-10, 0-25, 0-50, 0-100	0-10, 0-25, 0-50, 0-100
Work Period (seconds)	1-80 in 1 second increments	1-80 in 1 second increments
Rest Period (seconds)	0-80 in 1 second increments	0-80 in 1 second increments
Session Duration (minutes)	1-60 in 1 minute increments	1-60 in 1 minute increments

****NOTE** IEC 601-1 (except Amendment 2:1995, new subclause 56.3c)
 IEC 601-1-1
 IEC 601-2-10 (except Paragraph 36)
 EN 60601-1-2/IEC 601-1-2
 EN 55011/CISPR 11
 EN60801-2/IEC 801-2, 3kv contact, 8kv air
 IEC 801-3, 3v/m, 1 khz
 IEC 801-4, 1kv
 IEC 801-5, 1kv

7. Conclusion

Based upon the information presented above it is concluded that the proposed InCare Pelvic Floor Therapy System with Desktop Computer is safe and effective for its intended use and is substantially equivalent to the predicate device.